

U.S.S.N. 09/991,152

Filed: November 16, 2001

AMENDMENT AND RESPONSE TO OFFICE ACTION**Remarks**

New Claim 30 has been added to define the method of collecting the 3-hydroxy acids secreted into the medium from the organism as defined by claim 29, which is a subset of the organisms of claim 10. Support for this amendment can be found in the specification at least at page 20, lines 13-16.

Rejection Under 35 U.S.C. § 103

Claims 1-26 and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,750,848 to Kruger, et al. ("Kruger"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The Legal Standard

The U.S. Patent and Trademark Office has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Warner et al.*, 379 F.2d 1011, 154 U.S.P.Q. 173, 177 (C.C.P.A. 1967); *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988). **To establish a *prima facie* case of obviousness, three basic criteria must be met.** First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

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Claims for an invention are not *prima facie* obvious if the primary references do not suggest all elements of the claimed invention and the prior art does not suggest the modifications that would bring the primary references into conformity with the application claims. *In re Fritch*, 23 U.S.P.Q.2d, 1780 (Fed. Cir. 1992); *In re Laskowski*, 871 F.2d 115 (Fed. Cir. 1989). This is not possible when the claimed invention achieves more than what any or all of the prior art references allegedly suggest, expressly or by reasonable implication.

The Factual and Legal Analysis

It is clear that to establish a rejection under 35 U.S.C. § 103 the cited references must (1) recite each element of the claims, (2) provide one of skill in the art with the motivation to modify the cited reference and (3) provide one of ordinary skill in the art with a reasonable expectation of success. Kruger clearly does not meet all three criteria.

Kruger discloses *phaG* as a component in PHA synthesis via *de novo* fatty acid biosynthesis in *Pseudomonas putida*. Kruger discloses *phaG* as encoding a 3-hydroxyacyl-ACP-CoA transferase activity useful for producing (D)-3-hydroxyacyl-CoA precursors for the biosynthesis of polyhydroxyalkanoate (PHA).

(1) Recite Each Element Of The Claims

Kruger does not disclose or suggest transgenic organisms that express a transgene encoding an enzyme having the catalytic activity of 3-hydroxyacyl-ACP thioesterase and expressing one or more transgenes encoding enzymes having the catalytic activity of acyl-CoA synthetase or acyl CoA transferase that accumulate medium chain length polyhydroxyalkanoates through the fatty acid biosynthesis pathway.

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Furthermore, Kruger does not disclose or suggest methods of engineering a PHA biosynthetic pathway or methods of producing PHAs using transgenic organisms expressing a transgene encoding an enzyme having the catalytic activity of 3-hydroxyacyl-ACP thioesterase and expressing one or more transgenes encoding enzymes having the catalytic activity of acyl-CoA synthetase or acyl CoA transferase.

Since Kruger does not disclose each and every element of the claims of the application, as amended, the claims are not obvious over Kruger.

(2) Provide One of Skill in the Art with the Motivation to Modify the Reference and Provide One of Skill in the Art with a Reasonable Expectation of Success

Kruger states that proteins involved in the production of PHAs **might** be useful in engineering bacteria and plants. However, Kruger does not disclose which enzymes involved in the production of PHAs **are** useful for production of PHAs in bacteria or plants. Therefore, it would not be obvious to one of ordinary skill in the art as to which enzymes would be useful to produce PHAs in bacteria or plants in light of Kruger. In contrast to Kruger, the specification of the present application, at least at examples 1 to 9 (pages 17-34) disclose methods of producing transgenic bacteria or plants for medium chain length PHA production through the fatty acid biosynthesis pathway.

Furthermore, Kruger does not enable one of ordinary skill in the art to produce medium chain length PHAs in bacteria or plants. Kruger discloses that *phaG* can be used in conjunction with PHA synthase to produce PHA. However, Applicants have demonstrated at least at Example 2, that expression of *phaG* and a PHA synthase in bacteria did not result in PHA

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production. As defined by the claims, as amended, and as demonstrated by Applicants at least in Example 4, there is a requirement for supplemental acyl CoA synthetase or acyl CoA transferase activity for polymer production. Example 4 demonstrates that *phaG* is acting *in vivo* as a 3-hydroxyacyl ACP thioesterase and not as a 3-hydroxyacyl-ACP-CoA transferase as suggested by Kruger.

Finally, one of ordinary skill in the art would not be motivated to arrive at the claims of the present application because Kruger does not provide one of ordinary skill in the art with a reasonable expectation of success that acyl CoA synthetase or acyl CoA transferase activity is required for PHA production. Therefore, the claims of the present application are not obvious over Kruger.

Allowance of claims 1, 3-13, 15-20, 22-26 and 29 is respectfully solicited.

Respectfully submitted,



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